DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0182]

Draft Guidance for Industry on Combination Products, Timeliness of Premarket Reviews, Dispute Resolution; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance.'' The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) delegates to the Office of Combination Products (OCP) responsibility for resolving disputes about the timeliness of premarket review of combination products. This guidance document provides information about presenting requests for resolution of disputes about the timeliness of premarket review of combination products.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne O'Shea, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–827–9229; or

Sheryl Lard-Whiteford, Center for Biologics Evaluation and Research (HFM–4), 1401 Rockville Pike, Rockville, MD 20857, 301–827–5413; or

Les Weinstein, Center for Devices and Radiological Health (HFZ–5), 9200 Corporate Blvd., Rockville, MD 20850, 301–827–7991; or

Warren Rumble, Center for Drug Evaluation and Research, 5515 Security Lane, suite 500, Rockville, MD 20852, 301–594–5480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Combination Products, Timeliness of Premarket Reviews, Dispute Resolution Guidance.'' MDUFMA delegated to OCP responsibility for resolving disputes about the timeliness of reviews of premarket applications covering combination products. This guidance document provides information on how an applicant submitting an application(s) covering a combination product can submit a request that OCP resolve such a dispute.

A timeliness dispute arises when FDA does not review and act on an applicant's combination product application within the applicable performance goal set by the Prescription Drug User Fee Act (PDUFA) or

MDUFMA. Under PDUFA and MDUFMA, it is not expected that every application will meet every performance goal. Applications covering combination products in particular often present challenging review and regulatory issues. Nevertheless, because the PDUFA and MDUFMA performance goals reflect current review time expectations, it is appropriate to use them as guidelines.

The purpose of a timeliness dispute resolution request is to obtain the relevant review as quickly as possible, rather than to impose any sanction on the reviewing Center. In keeping with this perspective, upon receipt of a request for resolution of a timeliness dispute, OCP will contact the Center reviewing division and the Center Ombudsman to determine the current status of the review and what OCP can do to facilitate completion of the review as quickly as possible. If necessary and feasible, a plan for the completion of the review, including a target date for completion, will be developed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on combination products, timeliness of premarket reviews, and dispute resolution. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in

brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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